MAY 07 2002

510(K) SUMMARY

As required by 512(I)(3)(A) of the Food, Drug and Cosmetic Act, PrISMedical Corporation is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." PrISMedical chooses to submit a summary of safety and effectiveness information.

Applicant	PrISMedical Corporation 1100 Trancas Street, Suite 250 Napa, CA 94558 Phone: (707) 258-8666 FAX: (707) 258-0115 **Contact Person:** Elaine Alambra
Tradename	**MainStream™ Water Purification Device**
Device Generic Name	Water Purification Device
Classification / Classification Name	To be determined
Predicate Device	Total Water Treatment Systems (TWTS) – K002045
Product Description	PrISMedical's MainStream™ Water Purification Device (WPD) is a single-use device that will take approximately 3000 mL of drinking water (EPA-grade or equivalent) and remove: • particulates • dissolved solids • organics and inorganics • microbial contaminants • endotoxins

to produce water that meets the quality attributes of USP sterile purified water. This device comes in a 260-mL size to provide up to 3-liters of Sterile Purified Water, USP.

The device incorporates several complementary processes:

- Prefiltration
- Depth filtration
- Deionization
- Sterilizing membrane filtration

Intended use

To produce from EPA-grade drinking water, sterile purified water to be used within 24 hours of collection that is suitable for:

- cleaning and rinsing open wounds;
- infection control (cleaning equipment used in medical procedures, medical personnel's hands);
- use as a diluent for enteral, nutritional, oral vaccine,or oral drug preparations; and
- all other uses of sterile purified water the practitioner or clinician deems necessary.
- Not for parenteral administration.

Safety and Performance

Safety and functionality for this device were based solely on end product water characteristics. The materials, performance specifications and essential design characteristics of PrISMedical's MainStream™ water purification device are essentially identical to those of the Total Water Treatment Systems (TWTS) – K002045 predicate device. Both devices produce water

that meets the standards of USP Sterile Purified Water.

Conclusion

Based on the results of our testing and comparison of the requirements of the end product of the predicate device to compendial standards (Sterile Purified Water, USP), PrISMedical's MainStream™ Water Purification Device has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 07 2002

Ms. Elaine Alambra
Director, RA/QA
PrISMedical Corporation
1100 Trancas Street
NAPA CA 94558

Re: K012716
Trade/Device Name: PrISMedical's MainStream™ Water Purification Device (WPD)
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 NHV
Dated: March 7, 2002
Received: March 11, 2002

Dear Ms. Alambra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K012716**

Device Name: MainStream™ Water Purification Device

Indications for Use: To produce from EPA-grade drinking water, sterile purified water to be used within 24-hours of collection that is suitable for:

- cleaning and rinsing open wounds;
- infection control (cleaning equipment used in medical procedures, medical personnel's hands);
- use as a diluent for enteral, nutritional, oral vaccine or oral drug preparations; and
- all other uses of sterile purified water the practitioner, or clinician deems necessary.
- Not for parenteral administration.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
K012716

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012716